PATENT
Attorney Docket No. 62785.000005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

LE PAGE, RICHARD, *et al.*

Serial Number: 09/769,736

Filed: January 26, 2001

For: NUCLEIC ACIDS AND PROTEINS FROM GROUP B STREPTOCOCCUS

Group Art Unit: 1637

Examiner: S. CHUNDURU

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132

Sir:

I, Jeremy Wells state and declare as follows:

1. I have been awarded the degrees of BSc., PhD, and MBA

2. I am a Director of Microbial Technics,

3. I have 15 years of research experience in the field of Infectious Disease and that experience includes industrial research and development in Streptococcal vaccines.

4. Based on my education and professional experience, I consider myself to be a person of ordinary skill in the art of this patent application.

5. It was asserted in the Office Action issued March 31, 2004, in the subject application that the application fails to comply with the enablement requirement because, according to the text of the Office Action, "ID-38 (SEQ ID

NO: 72) has not been shown to have any activity, or to be useful as a vaccine against [Group B Streptococcus] challenge... Thus, it is not predictable if ID-38 (SEQ ID NO: 72) can be used as a vaccine or not." Office Action, page 4.

6. I have supervised the performance of experiments in which CBA/CA mice (10 per group) were immunized subcutaneously with 25 micrograms of ID-38FL or ID-38TF protein formulated in an equi-volume mix with alum adjuvant (final volume 200 microliters). ID-38FL is the full-length protein consisting of 861 amino acids, and comprising the 485 amino acids of SEQ ID NO:72. ID-38TF is the truncated fragment of ID-38FL consisting of 516 amino acids, and comprising the 485 amino acids of SEQ ID NO:72. Control mice received 25 micrograms of Bovine Serum Albumin (BSA) mixed with alum. All the mice were given a second dose (same volume and formulation as the first) after 4 weeks and challenged 3 weeks later with a lethal dose of Group B Streptococcus (7.5×10^6 colony forming units).

7. Of the 10 control mice (BSA only), only one survived 168 hours post-challenge, and the average mouse lived only 37.95 hours post-challenge. Of the 10 mice immunized with ID-38FL, seven survived 168 hours post-challenge, and the average mouse lived 125.57 hours post-challenge. Of the 10 mice immunized with ID-38TF, eight survived 168 hours post-challenge, and the average mouse lived 143.47 hours post-challenge.

8. Both ID-38FL and ID-38TF were shown to provide prophylactic immunization to Group B Streptococcus infection compared to the negative control. Based on this experimental confirmation, as a person skilled in vaccine

development, I believe that ID-38FL or ID-38TF have useful activity as a vaccine against Group B Streptococcus.

9. The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and may jeopardize the validity of the application or any patent issuing thereon.

Date: 17th August 2004 By: J. Wells

Dr J. WELLS